July 27, 2020

Codman & Shurtleff, Inc.
Amarilys Machado
Sr. Manager, Regulatory Affairs
325 Paramount Dr.
Raynham, Massachusetts 02767-0350

Re: K132281
Trade/Device Name: ReVive PV (Peripheral Vasculature) Thrombectomy Device
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW

Dear Amarilys Machado:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 30, 2013. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2020.07.27 08:19:38 -04'00'

Gregory O'Connell
Assistant Director
Plaque Modification Devices Team
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

April 29, 2019

Codman & Shurtleff, Inc.
Amarilys Machado
Sr. Manager, Regulatory Affairs
325 Paramount Dr.
Raynham, MA 02767

Re: K132281
Trade/Device Name: Revasc Thrombectomy Device
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: July 22, 2013
Received: July 23, 2013

Dear Ms. Amarilys Machado:

This letter corrects our substantially equivalent letter of August 30, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Gregory O'Connell 2019.04.29 12:59:52 -04'00'

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4.

INDICATIONS FOR USE STATEMENT

510(k) Number:
K132281

Device Name: ReVive™ PV Thrombectomy Device

The ReVive™ PV Thrombectomy Device is indicated for:

- The non-surgical removal of emboli and thrombi from peripheral blood vessels,
- The non-surgical removal of thrombi from synthetic grafts,
- Temporary use in peripheral vessel/graft occlusion,
- Use with aspiration and with the injection or infusion of contrast media and other fluids

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
2013.08.30 12:47:01 -04'00'

SECTION 5.
510(k) SUMMARY

(As Required By 21 CFR 807.92(a))

A. Company Information

Company Name: Codman & Shurtleff, Inc.
Address: 325 Paramount Drive
Raynham, MA 02767
Telephone: (305) 265-6869
Fax: (305) 265-6889
Contact Person: Amarilys Machado
Date of Submission: July 22, 2013

B. Trade/Device Name: The ReVive™ PV Thrombectomy Device
Common Name: Embolectomy Catheter
Classification Name: Embolectomy Catheter
Regulation Number: 21 CFR 870.5150
Product Code: DXE

C. Predicate Device Information:

Table 1. Prior 510(k) Clearances

510(k) Number	Date Cleared	Name	Manufacturer
K092623 **Predicate**	10/30/09	F.A.S.T. System SED (Self Expanding Device) and F.A.S.T CXD (Controlled Expansion Device)	Genesis Medical Interventional Inc.*

*On 01/18/10, certain assets of Genesis Medical Interventional Inc. were acquired by Micrus Endovascular Corporation. Effective 09/27/10, Micrus Endovascular Corporation was acquired by Johnson & Johnson and now operates as a wholly-owned subsidiary of Codman & Shurtleff within the Johnson & Johnson family of companies.

D. Device Description:

The ReVive™ PV (Peripheral Vasculature) Thrombectomy Device is a sterile, disposable, thrombectomy device that is intended to restore blood flow via non-surgical removal of emboli and thrombi from peripheral blood vessels, non-surgical removal of thrombi from synthetic grafts and also for temporary use in peripheral vessel/graft occlusion. The ReVive™ PV Thrombectomy Device is radiopaque so that fluoroscopy can be used to guide insertion and verify position as necessary.

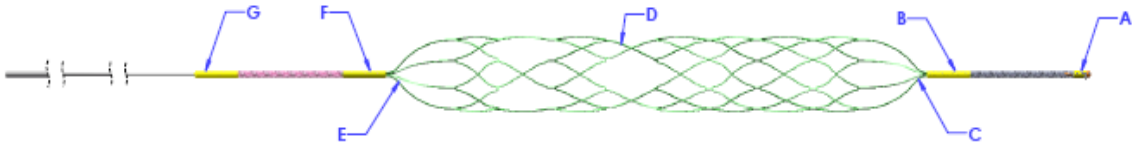
The ReVive™ PV Thrombectomy Device consists of a self-expanding Nitinol basket attached to a core pusher wire. Platinum markers at the proximal and distal ends of the basket facilitate visualization under fluoroscopy. A flexible radiopaque tip is attached to the distal aspect of the basket.

The ReVive™ PV Thrombectomy Device is provided as a sterile device and is intended for single patient use only. It is not intended to be resterilized and/or reused. No accessories are provided with the ReVive™ PV Thrombectomy Device. The system is used in conjunction with the appropriately sized microcatheter, as indicated in the proposed Instructions for Use.

An overview of the main components comprising the ReVive™ PV Thrombectomy Device is presented in Table 2, followed by illustrative representation in Figure 1.

Table 2. ReVive™ PV Thrombectomy Device Components	
Component*	**Description**
Introducer Sheath	The device is packaged such that the basket is constrained within a polymer introducer sheath. The device is designed to be front-loaded via the introducer sheath into the proximal hub of a 0.027 inch inner diameter microcatheter.
Soft Distal Tip (A)	A short atraumatic guidewire type element extends distal to the distal termination of the basket. The Soft Distal Tip also has a platinum maker affixed for visualization purposes.
Distal (B)/ Proximal (F) Radiopaque Marker	As stated above, the Distal Tip serves as the distal radiopaque marker using a platinum coil. The proximal radiopaque marker is also provided via a platinum coil, covering the tapered portion of the core pusher wire from the proximal junction of the basket and extending 13cm proximally.
Distal End / Distal Mesh (C)	The basket terminates distally to the Soft Distal Tip radiopaque marker as a mesh having a higher strut density than the proximal end.
Basket (D)	A permanently affixed self-expanding basket element. The basket is attached near the distal end of the pusher wire. The basket is self-expanding when deployed out of the microcatheter and reduces into the microcatheter when reconstrained.
Proximal End / Proximal Mesh (E)	The basket terminates proximally to the core pusher wire as a mesh having a lower strut density than the distal end.
Core Pusher Wire (G)	The proximal portion of the core pusher wire is similar to a standard core pusher wire. The remaining distal portion of the core pusher wire is tapered to a smaller diameter and is attached to the “Basket”.
*The letters following the component name refer to the letters used in Figure 1.	

Figure 1. Basket Design and Distal Tip



A. Soft Distal tip
B. Distal radiopaque marker
C. Distal end / Distal mesh
D. Basket
E. Proximal end / Proximal mesh
F. Proximal radiopaque marker
G. Core pusher wire

E. Intended Use:

The ReVive™ PV Thrombectomy Device is indicated for:

- The non-surgical removal of emboli and thrombi from peripheral blood vessels,
- The non-surgical removal of thrombi from synthetic grafts,
- Temporary use in peripheral vessel/graft occlusion,
- Use with aspiration and with the injection or infusion of contrast media and other fluids

F. Summary of technological characteristics of the proposed device to the predicate device:

The ReVive™ PV Thrombectomy Device, (the basket, core pusher wire, radiopaque markings and introducer sheath), is identical to the predicate F.A.S.T System SED with regard to design, material, function, mechanism of action, clinical utility and manufacturing processes.

Compared to the predicate device, device modifications for the ReVive™ PV Thrombectomy Device include a change of sterilization method and product shelf life, and modifications to product labeling and packaging. Labeling changes are focused on re-branding the product with updated directions for use, including clarification and simplification of the product intended use and directions for use.

Table 3 provides a comparison of the regulatory information and intended use for the predicate and subject devices.

No new technological characteristics are being introduced with the proposed device.
A summary table including characteristics of the proposed device compared with those of the predicate device is provided in Table 4.

Characteristic	F.A.S.T. System SED (Predicate Device)	ReVive PV Thrombectomy Device (Subject Device)
510(k) Number	K092623	To Be Assigned
Clearance Date	10/30/09	To Be Assigned
Classification Name	Embolectomy Catheter	Embolectomy Catheter
Product Code	DXE	DXE
FDA Regulation	870.5150	870.5150
Indication	• The non-surgical removal of emboli and thrombi from blood vessels, • The non-surgical removal of thrombi from synthetic grafts, • Temporary use in vessel/graft occlusion, • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a vessel/graft, and • Catheter placement over a guidewire	• The non-surgical removal of emboli and thrombi from peripheral blood vessels, • The non-surgical removal of thrombi from synthetic grafts, • Temporary use in peripheral vessel/graft occlusion, • Use with aspiration and with the injection or infusion of contrast media and other fluids

Table 4. Comparison of Subject and Predicate Devices: Device Characteristics		
Characteristic	**F.A.S.T. System SED** (Predicate Device)	**ReVive PV Thrombectomy Device** (Subject Device)
GENERAL DESIGN		
Thrombectomy Mechanism	Compressed basket deployment	Same as predicate device
Microcatheter compatibility	0.021 inch (0.533 mm) Inner Diameter microcatheters	0.027 inch (0.686 mm) Inner Diameter microcatheters
Guidewire compatibility	0.014 inch systems	Same as predicate device
Introducer Mechanism	Introducer sheath and core pusher wire	Same as predicate device
Radiopacity	Proximal and distal end markers	Same as predicate device
Sterilization method	Ethylene Oxide	eBeam Irradiation
Shelf Life	1 year	3 years
MATERIALS		
Distal Tip	Nitinol, platinum	Same as predicate device
Catheter hub	Nylon	Same as predicate device
Core pusher pusher Wire	Nitinol	Same as predicate device
DIMENSIONS		
Basket length	22 mm – 28 mm; full expansion into sheath/microcatheter (engaging portion)	Same as predicate device
Basket Diameter	0.6 mm (in sheath/microcatheter)	Same as predicate device
Basket Working Length	22 mm to 28 mm for 1.5 mm to 5.0mm vessel range.	Same as predicate device
Expanded Basket Diameter	4.5 mm	Same as predicate device
Distal Tip Length	6 mm	Same as predicate device
PACKAGING		
Configuration	1, 5 or 10 pouched devices and one (1) IFU into one (1) carton	One (1) device and one (1) IFU placed into one (1) carton
Protective enclosure	Device placed into PETG formed tray	Device placed into a medical grade polyethylene dispenser hoop with a thermoplastic clip to hold the wire
Sterility barrier	Tyvek/polyethylene film thermo sealed pouch	Polyester Film/LD Polyethylene thermo sealed pouch
Labels	Inner (pouch) and outer (carton)	Same as predicate device
Carton	Chipboard box	Reverse tuck end style carton with thumb notch, 24 point chipboard

G. Summary of Nonclinical Testing:

No new technological characteristics are being introduced with the proposed ReVive™ PV Thrombectomy Device and the design, materials, mechanism of action, performance specifications, and clinical utility of the device are the same as the predicate device (K092623). Codman performed non-clinical testing necessary to demonstrate substantial equivalence to the predicate device. Bench testing was conducted using the same test methods as the predicate device. Resulting data demonstrated that the ReVive™ PV Thrombectomy Device performed according to the established performance characteristics of the predicate device.

Bench Testing

In alignment with the Design Risk Assessment, verification and validation testing was identified as appropriate to support device modifications. This testing demonstrated equivalence between the proposed and predicate device, and also that modifications made had no impact to device performance.

The following verification and validation testing was conducted:

- Radial Force Test
- Tip Deflection Force
- Rapid Flow Restoration
- Corrosion
- Tensile Testing
- Track Test
- Cyclic Fatigue
- Deploy and Recapture
- Torsion
- Force for Recapture

- Biocompatibility testing in accordance with ISO 10993-1: 2009
  - Cytotoxicity
  - Sensitization
  - Pyrogenicity
  - Irritation: Intracutaneous Reactivity
  - Acute Systemic Toxicity
  - Hemocompatibility: hemolysis

- Thrombogenicity
- Complement Activation
- Partial Thromboplastin Time (PTT)

- Sterilization method validation in accordance with ISO 11137: 2006
  - Bioburden measurement
  - Identify top three organisms
  - Bioburden recovery study (Extraction efficiency)
  - Verification dose experiment
  - Bacteriostasis/Fungistasis (B/F)
  - Confirmatory dose experiment (if Sterility Test fails)
  - LAL Validation

- Packaging Validation in accordance with ISO 11607-1: 2006 and ISO 11607-2: 2006
  - Package Integrity Testing
  - Dye Leak
  - Seal Strength Testing

Test results demonstrated that all acceptance criteria were met, and, therefore, the ReVive PV Thrombectomy Device conforms to expected device performance and intended use.

H. Summary of Clinical Testing:

No clinical studies were required as appropriate verification and validation of device modifications were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

Conclusion:

Based upon the design, materials, function, intended use, and the non-clinical testing performed by Codman & Shurtleff, Inc., it is concluded that the ReVive™ PV Thrombectomy Device is substantially equivalent to the F.A.S.T. System SED, and therefore, does not raise any new questions of safety and effectiveness.